

## REMARKS

In response to the Examiner's objection to the improper printing of the last four pages of the specification, applicant has repaginated the application and enclosed herewith is a reprinted, repaginated substitute copy of the application. Applicant requests that this substitute, reprinted copy of the application be substituted in place of the application originally filed. The substitute application, except for pagination is identical to the originally filed application and does not contain any new matter.

The Examiner's rejection to claim 5, is overcome by the amendment of dependency claim 5 set forth above.

In response to the Examiner's rejection of claims 1 and 2 under 35 U.S.C. §112 for being indefinite on the grounds that the term "super" is not clear to the Examiner, applicant has amended claims 1 and 2 to delete the term "super" and to define the balloon as having a high strength for resisting of bursting during over inflation. In other words, the balloon has a high tensile strength.

In any event, it should be clear from the specification that "super" means improved strength and that applicant obtains a high-strength balloon by using reinforced polymers and nano materials, i.e. nanoclay, carbon nanoclay or ceramic nano materials.

The Examiner's rejection to claim 2 under 35 U.S.C. §112 for being indefinite because of the use of the language "nylon or 12" is believed to be overcome by the amendment of the language to --nylon 12 or--.

The Examiner's rejection of claims 1-15 under 35 U.S.C. §102(e) for being anticipated by the Weber Published U.S. Patent Application No. US 2003/0065355A1, as this rejection may be attempted to be applied to the amended claims, is respectfully traversed.

In support of this traverse, applicant is submitting herewith a Declaration under Rule 131 by the applicant/inventor, Mr. Oscar Jimenez.

In his Declaration, Mr. Jimenez, points out that he had conceived of his super balloon in the spring of 2001.

Further he states that he constructed a balloon with nanotubes therein as early as June 2001. A copy of a purchase order for materials for making the super balloon and a picture of the super balloon are attached to his Declaration.

Applicant submits that upon entry and acceptance of the Declaration submitted herewith under Rule 131, the Weber publication should be withdrawn as a citable reference against the claims of the subject application.

Further, once this is done applicant submits that the application will be in condition for allowance. An early and favorable action to that end is requested.

Respectfully submitted,

December 24, 2003

Date

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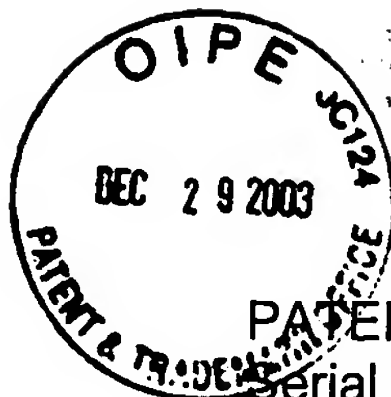
Thomas R. Vigil  
Registration No. 24,542

WELSH & KATZ, LTD.  
120 SOUTH RIVERSIDE PLAZA  
22<sup>nd</sup> Floor  
CHICAGO, IL 60606-3912  
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Telephone: 1-312-655-1500  
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Email: trvigil@welshkatz.com

I hereby certify that this paper is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop \_\_\_\_\_, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date.

Date

Registration No. 29,542  
Attorney for Applicant(s)



PATENT APPLICATION

Serial No. 10/046,452

Attorney Docket No. 8449-86523

RECEIVED

JAN 07 2004  
TC 1700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Oscar Jimenez

Serial No.: 10/046,452

Filed: January 14, 2002

Title: Angioplasty Super Balloon  
Fabrication With Composite Materials

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)  
) Group Art Unit: 1772  
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)  
) Examiner: Sandra M. Nolan  
)  
)  
)  
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)  
)  
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**DECLARATION OF OSCAR JIMENEZ UNDER RULE 131**

TO: Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Oscar Jimenez, residing at 8000 Los Pinos Boulevard, Coral Gable, Florida 33143 declare as follows:

1. I am the inventor in the above-identified patent application.
2. During the spring of 2001, I conceived the idea of making a reinforced balloon which I called a super balloon and which was made of a nano-composite reinforced polymer including a polymer and one of carbon nano-tubes, a nano-clay or nano-ceramic fibers formed into a balloon for medical applications, i.e., angioplasty, and having an increased tensile strength over balloons already in the marketplace.
3. I then proceeded to make such a super balloon and ordered nanocomposite pellets from Foster Corporation for use in fabricating

the balloon. Attached and marked Exhibit 1 is a copy of a Purchase Order to Foster Corporation dated May 22, 2001, for the purchase of nanocomposite pellets. Also attached, as Exhibits 2 and 3, are copies of photographs of some of the pellets left over from that purchase.

4. In June 2001, I fabricated a balloon and attached are Exhibits 4-6 which are photographs of the balloon I manufactured in June of 2001.
5. I then prepared an Invention Disclosure that I proceeded to send to my patent attorney, Mr. Thomas Vigil. Attached as Exhibit 7 is the first page of a second draft of the Invention Disclosure having a date of July 15, 2001 and as Exhibit 8 is a copy of the first page of a final draft of the Invention disclosure dated July 18, 2003.
6. Further I faxed my attorney on July 24, 2001 requesting that we add nano-scale ceramic fibers to my Invention Disclosure. Enclosed as Exhibit 9 is a copy of my Fax dated July 24, 2001
7. The foregoing statements and attached documents show that I had conceived and reduced to practice before July 1, 2001 my super balloon comprising a nano-composite reinforced polymer including a polymer and one of carbon nano-tubes, a nano clay or nano-ceramic fibers for medical applications and having a high strength for resisting bursting during over inflation.

Further, I declare under the penalties of perjury under the laws of the United States of America that the above statements are true and correct and that those made on information and belief are believed to be correct and any false statements so made herein will affect the validity of the subject patent application or the patent issuing thereon.

December 24, 2003  
Date

\_\_\_\_\_  
Oscar Jimenez

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JAN 07 2004

TC 1700

Confidential

**VasCon** CARDIOVASCULAR  
INSTRUMENTATION

**VasCon, LLC**

9344 NW 13 Street Suite 200  
Miami Florida 33172-2808

www.vasconllc.com  
Ph.: 305/477-2406

Fax: 305/592-6605  
Fax: 305/592-0826

PURCHASE REQUISITION No: Do Not Fill  
PURCH. ORDER DATE: Do Not Fill  
APPROVED VENDOR REQUIRED - (YES/NO): YES  
ACCOUNTS PAYABLE SYSTEM - ACCOUNT No: Do Not Fill  
VENDOR ASSIGNED ACCT. TO CATHION No: Do Not Fill

PUR. REQ. DATE: 22-May-2001

**Vendor**

Name: Janet  
Company: Foster Corporation  
Address: 329 Lake Road, PO Box 997  
City: Dayville St: CT ZIP: 06241  
Phone: (860) 774-3964 Fax: (860) 779-0805  
E-mail: [foster.corp@fostercomp.coi](mailto:foster.corp@fostercomp.coi)

**Requisitioned by / Ship To**

Name: Cliff Taylor  
Company: VasCon, LLC  
Address: 9344 NW 13 Street Suite 200  
City: Miami St: FL ZIP: 33172-2808  
Phone: 305/477-2406 X-111 Fax: 305/592-6605  
E-mail: [ctaylor@vasconllc.com](mailto:ctaylor@vasconllc.com) Fax: 305/592-0826

Qty	Units	Description	Unit Price	TOTAL
50	lbs	Grilamid L25-6086 + 5% Nanocomposite	25.0000	1,250.00

Foster to supply all raw materials

C of C Required with Shipment that includes:

- 1) Material and manufacturer name for each component.
- 2) Material lot number for each component.
- 3) Vendors identifying component lot Number.
- 4) Final percentage by weight of each component.



**Payment Information**

Credit Card: \_\_\_\_\_  
Name: \_\_\_\_\_  
Credit Card No: \_\_\_\_\_  
Exp Date: \_\_\_\_\_  
Check: \_\_\_\_\_  
On Account: **Do Not Fill**

**Please Provide  
Confirmation of  
Receipt of this  
Purchase Order**

SubTotal 1,250.00  
Shipping & Handling  
SubTotal + Sh. & Hndlg. 1,250.00  
Taxes (If Applicable)  
Other  
**TOTAL 1,250.00**

Vendor's Quote/Order No: Quote # 3893  
Sales Rep/Contact: Janet

**Shipping Information**

Carrier: \_\_\_\_\_ Date: \_\_\_\_\_

**This P.O. Approved by:**

Oscar Jimenez 00/00/00

**This P.O. is not valid without an authorized signature.**

**Dear Vendor:**

**To ensure prompt payment, please  
include our P.O. # in your Invoice  
and Packing List.**

**Remarks:**

1. A Certificate of Compliance or Certificate of Analysis is required: ☒ Yes ☐ No
2. An MSDS, if applicable, is required with shipment: ☐ Yes ☒ No
3. Supplier agrees to notify Cathion Corporation of changes in the product or service specifications or process so that Cathion Corporation may determine whether the changes may affect the quality of the finished device.

Requisitioned by Cliff Taylor

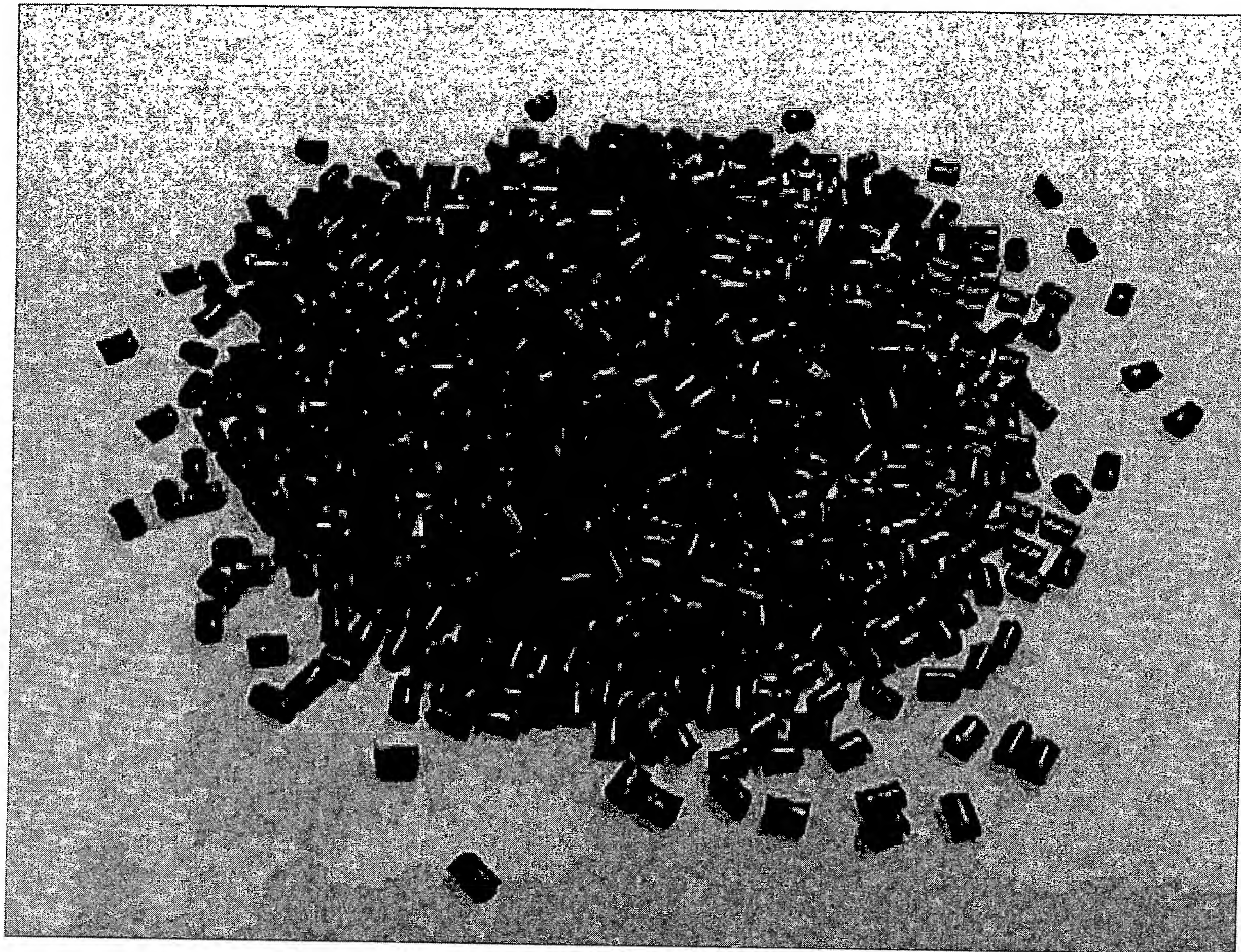
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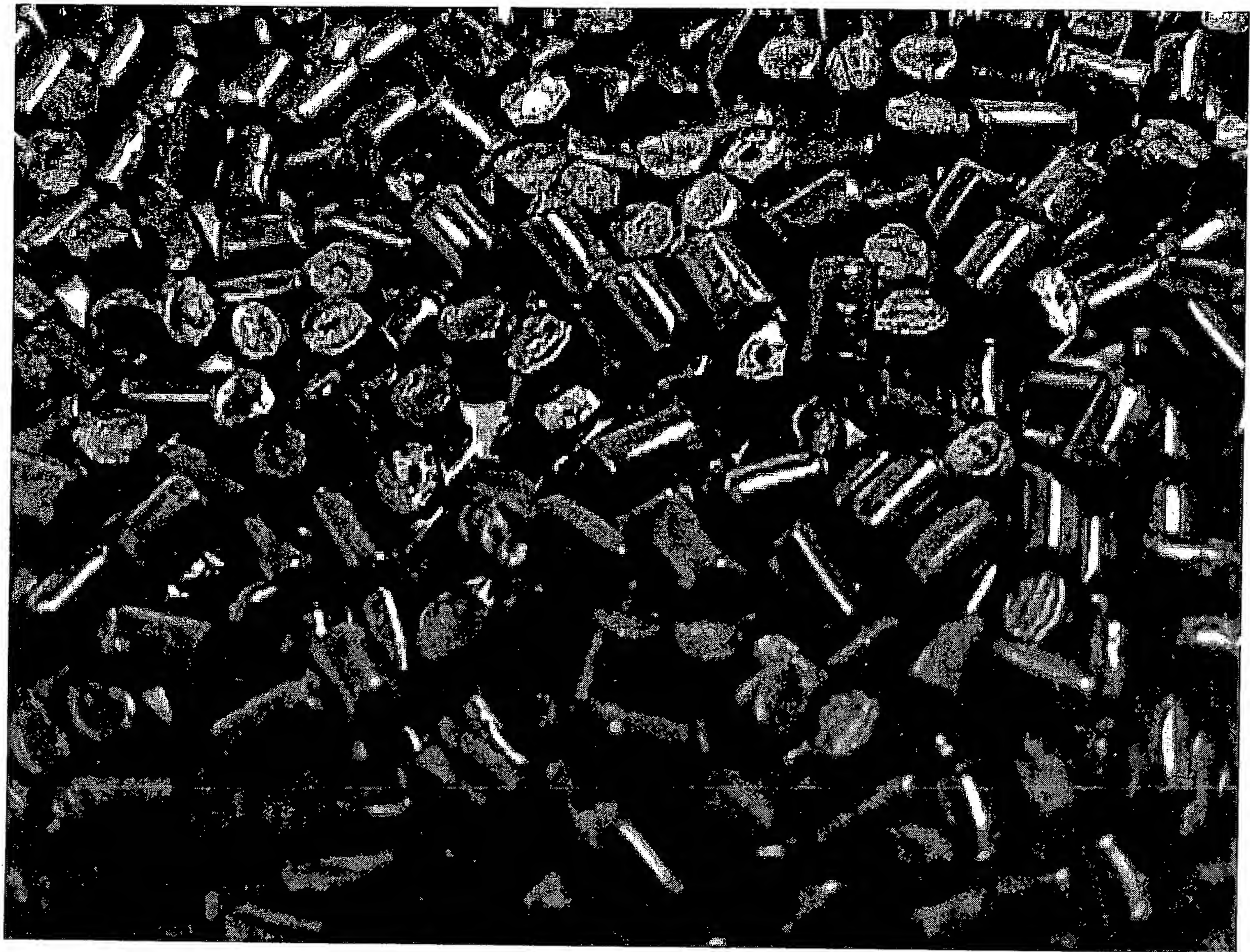
Foster PO 1.xls



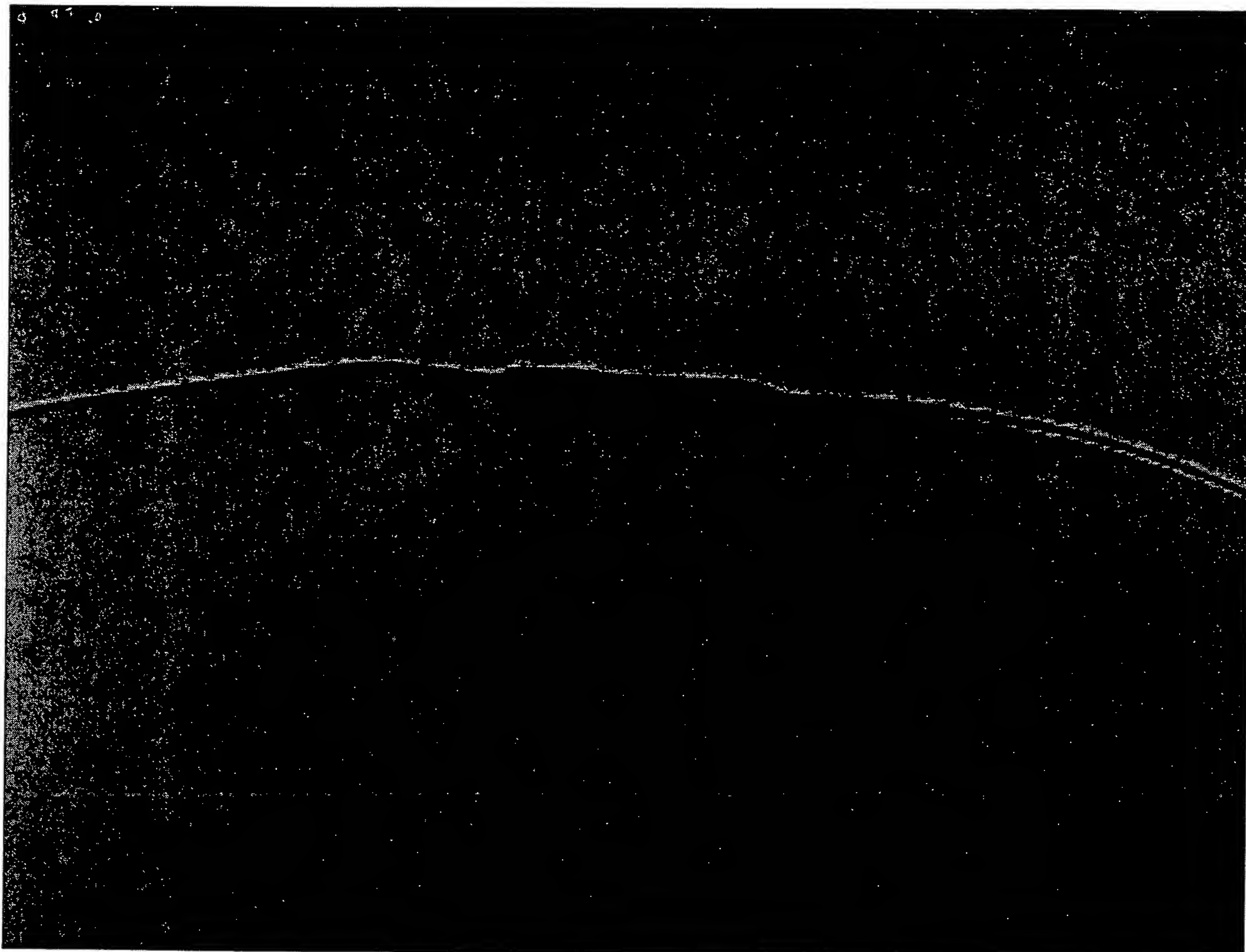


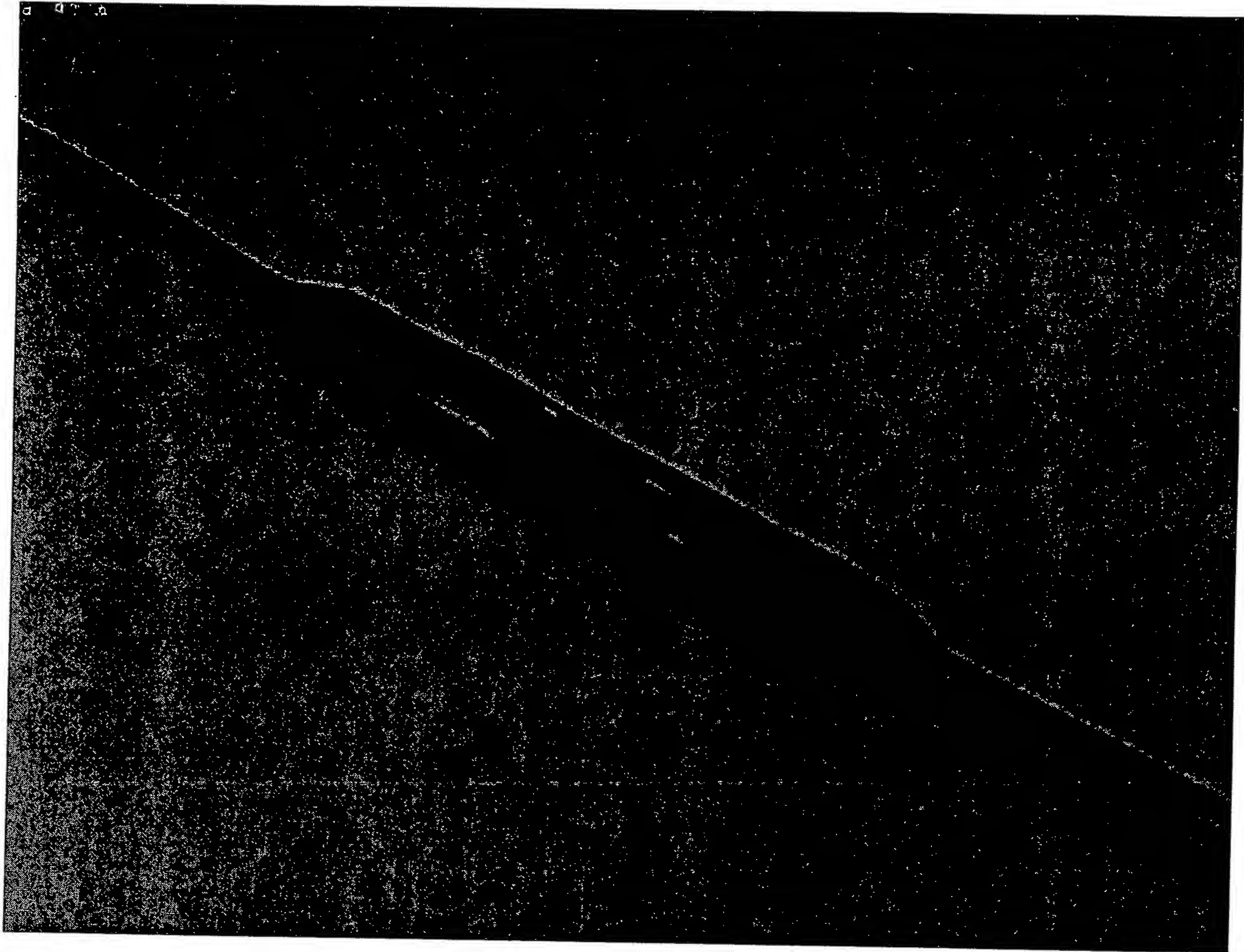


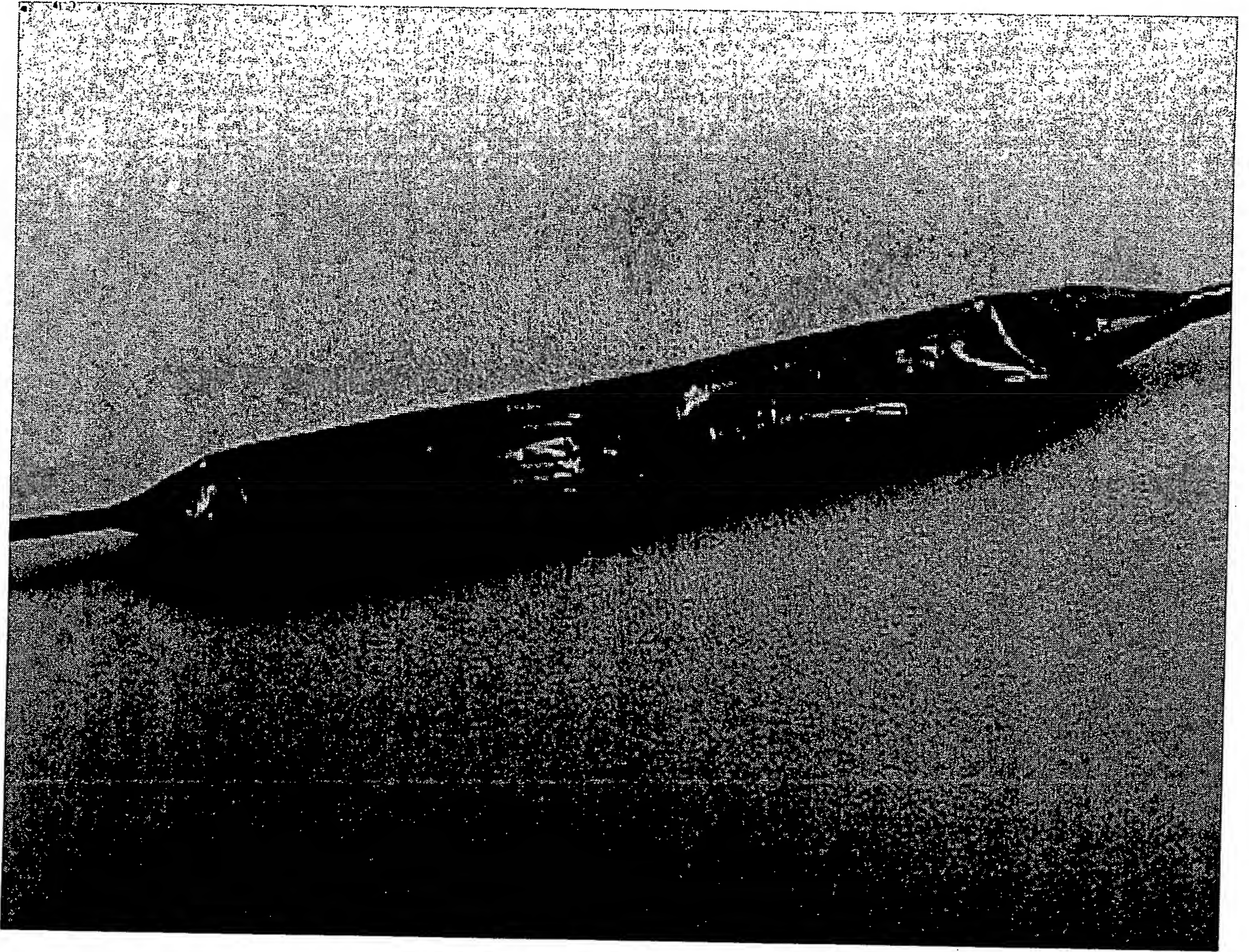














# ANGIOPLASTY BALLOON FABRICATION WITH COMPOSITE MATERIALS



Invention Disclosure  
Second Draft  
(July 15, 2001)

## ABSTRACT

Angioplasty balloons are required to be able to withstand very high pressures, which force the balloon's surface against various tissues and deposits representing a range of viscoelastic characteristics, and include some very hard and rough surfaces. As the balloons must be thin-walled to collapse into a small cross-section for introduction to the target area, the balloons must be made extremely strong and puncture resistant. The balloons also must expand in a predictable manner when the internal pressure is beyond the nominal value where the cross-section is rated. To meet these exacting requirements this patent disclosure presents a number of methods of creating composite films of organic polymers and inorganic additives on a nanometric scale. The preparation and formation of balloons using specifically carbon nanotubes and clay platelets is presented.

## BACKGROUND

Angioplasty addresses the problems of partially or fully obstructed arteries. Angioplasty balloons have been used by invasive cardiologists since the 1970s when Andreas Grunzig reported his data on reopening the occluded coronary arteries of five patients and that these arteries remained patent, open, allowing blood flow for six months or longer. The Grunzig procedure involved the introduction of a high-pressure angiographic catheter with a collapsed polymer balloon cemented to its distal portion. Once the catheter is positioned within the occluded range in the artery under fluoroscopic control, the balloon is pressurized, typically by injecting a fluid. The pressure in the balloon exerts pressure on the surrounding obstructive structures and enlarges the lumen, the cross section for blood flow. The balloon is depressurized until it collapses and it then can be withdrawn from the obstructed site where circulation has been restored through this maneuver.

As angioplasty, the reforming of blood vessels, has gained acceptance and replaced to a great extent the coronary artery bypass graft procedure, a major surgical intervention, the demands for the performance of the balloon catheter have increased. These demands include high strength to withstand pressures on the order of 10 to 20 atmospheres. In comparison, the typical passenger car's tires are inflated to about 32 psi or slightly above 2 atm. above the ambient pressure. While the typical tire wall is a composite, the walls are reinforced by high strength weaves of polyester filaments or stainless steel wires embedded in







CONFIDENTIAL  
INVENTION DISCLOSURE

ANGIOPLASTY SUPER BALLOON FABRICATION WITH  
COMPOSITE MATERIALS

Oscar Jimenez  
Cathion, LLC  
Miami, FL 33172

(Final Draft)  
(18 July 2001)

**ABSTRACT**

Angioplasty balloons are required to be able to withstand very high pressures, which force the balloon's surface against various vessel tissues and deposits representing a range of viscoelastic characteristics, and include some very hard and rough surfaces. As the balloons must be thin-walled to collapse into a small profile (cross-section) for introduction to the target area, the balloons must be made extremely strong and puncture resistant. The balloons also must expand in a predictable manner when the internal pressure is beyond the nominal value where the cross-section is rated. In additions, balloon catheters are also used to deploy metallic stents within a constricted vessel. Stents are expandable wire mesh devices that help retain proper vessel lumen after dilation. In this application, the balloon must come in contact with a metallic mesh that may inflict damage to the balloon. To meet these exacting requirements this intellectual property disclosure presents a number of methods of creating composite films of organic polymers and inorganic additives on a nanometric scale. The preparation





## TELEFAX

DATE: 24 July 2001

TO: Thomas Vigil

FAX NUMBER: (847) 382-6895

FROM: Oslar Jimenez

PAGES INCLUDING COVER: 2

RE: \_\_\_\_\_

MESSAGE: \_\_\_\_\_

\_\_\_\_\_

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\_\_\_\_\_

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## CONFIDENTIAL INFORMATION

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Cathion, LLC

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P. 01

305-592-0826

JUL-24-01 09:33A CATHION, LLC

FAX TO

TOM VIGIL

Tom:

I would like to  
add nanoscale ceramic  
fibers as a reinforcer  
for the super balloon  
patent. Please add  
language as required.

Regards,

OSCAR JIMENEZ

## NEWS & ANALYSIS

### Nanoscale Ceramic Fibers Smaller than DNA Molecule

Argonide Nanomaterials (Sanford, FL) has developed the first in a family of new products based on the use of alumina fiber. The fibers have a diameter of 2 nm, a surface area of 500-600 m<sup>2</sup>/g, and an aspect ratio (AR) ranging from 20 to 100. The company suggests that the small diameter and high AR makes the fibers "an ideal reinforcement for ceramic, metal, and plastic composites." The firm states that they are "smaller than the size of a DNA molecule," and suggests that they will be useful in reinforcing medical and dental devices.

Argonide indicates that the fibers, called Nanoceram, have diameters more than two orders of magnitude smaller than previously available discontinuous fibers.



*Smaller than a DNA molecule, alumina fibers can strengthen composites.*

The fibers have also resulted in significant increases in composite strength. Because the Nanoceram fibers have a higher surface area than particulate powders, the material is also expected to prove superior in forming ceramic membranes and membrane reactors.

This material was developed in collaboration with the Republican Engineering Technical Center in Tomsk, Siberia. Argonide indicates that it has a cooperative agreement with the U.S. Department of Energy to employ approximately 60 former Soviet scientists; three U.S. national laboratories also contributed to the development project.

